DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

January 2, 2015

Re: K143472
Trade/Device Name: TE7 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 31, 2014
Received: December 5, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K143472

Device Name
TE7

Indications for Use *(Describe)*

TE7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal,Intra-operative(abdominal, thoracic, and vascular) ,Pediatric,small organ(breast, thyroid, testes), neonatal and adult cephalic,trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), urology,Peripheral vessel, Adult and Pediatric cardiac exams.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications For Use Format

System: TE7 Diagnostic Ultrasound System

Transducer: N/A

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2
	Abdominal	N	N	N	N	N	N	N	Note 1,2
	Intra-operative (Specify*)	N	N	N		N	N	N	Note 1,2
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2
	Trans-rectal	N	N	N		N	N	N	Note 1,2
	Trans-vaginal	N	N	N		N	N	N	Note 1,2
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2
	Other (Specify***)	N	N	N		N	N	N	Note 1,2

N=new indication； P=previously cleared by FDA； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: C11-3s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k141010)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: C5-2s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2
	Abdominal	P	P	P		P	P	P	Note 1,2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: P7-3Ts

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P	Note 1
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: L12-4s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: L7-3s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: L14-6s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: L14-6Ns

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: P4-2s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	P	Note 1,2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,3
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(k131690); E=added under Appendix E									
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power									
*Intraoperative includes abdominal, thoracic, and vascular etc.									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of Device Evaluation(ODE)									

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: V11-3Ws

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1,2
	Trans-vaginal	P	P	P		P	P	P	Note 1,2
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	P	P	P		P	P	P	Note 1,2
N=new indication； P=previously cleared by FDA(k141010)； E=added under Appendix E									
Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power									
*Intraoperative includes abdominal, thoracic, and vascular etc.									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of Device Evaluation(ODE)									

Prescription USE (Per 21 CFR 801.109)

System: TE7 Diagnostic Ultrasound System

Transducer: 7LT4s

Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2
	Intra-operative (Specify*)	P	P	P		P	P	P	Note 1,2
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2
	Other (Specify***)								

N=new indication； P=previously cleared by FDA(k131690)； E=added under Appendix E

Additional comments： Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K143472.

1. Submitter:

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Date Prepared: October 29, 2014

2. Device Name: TE7 Diagnostic Ultrasound System

Classification

Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

TE7 is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, CW-Mode, Color-Mode , Power/Dirpower Mode, THI, LVO or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

This system is a Track 3 device that employs an array of probes that include linear array and convex array with a frequency range of approximately 3.0 MHz to 10.0 MHz.

4. Intended Use:

TE7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal,Intra-operative(abdominal, thoracic, and vascular) ,Pediatric,small organ(breast, thyroid, testes), neonatal and adult cephalic,trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), urology, Peripheral vessel, Adult and Pediatric cardiac exams.

5. Comparison with Predicate Devices:

TE7 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	M9	K141010
2	Mindray	M7	K131690

TE7 has the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

- Subject device TE7has the same intended uses as the predicated device M7(K131690)

Subject Device TE7	Predicate device M7(K131690)
TE7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), Pediatric,small organ(breast, thyroid, testes), neonatal and adult cephalic,trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), urology, Peripheral vessel, Adult and Pediatric cardiac exams.	The M7/M7T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, trans-cranial, cardiac, trans-vaginal, trans-rectal, peripheral vascular, urology, orthopedic, and muscular-skeletal (conventional and superficial), Intra-operative and Trans-esophageal (cardiac) exams.

- All of the patient contact material of the TE7are the same as that of the predicated device M7(K131690).
- The acoustic power levels of TE7 are below the limits of FDA, which is the same as the predicated device M7(K131690).
- TE7 is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device M7(K131690).
- TE7 has the same imaging modes as the predicated device M7(K131690): B, M, Color Doppler, PWD, CWD, Amplitude Doppler, Anatomical M Mode and combined mode).
- TE7 has some special functions: LVO, and iNeedle All of them are identical as the predicated device M9(K141010).
- TE7 has the same capacity in term of making comments and body marks on the images, reporting patient exam results as the predicated device M7(K131690).
- TE7 has similar probes as the predicated device M9(K141010) and M7(K131609):

Subject device TE7	Predicated device M9(K141010)	Predicated device M7(K131690)	NOTE
C5-2s	/	C5-2s	Same
L12-4s	/	L12-4s	Same

L7-3s	/	L7-3s	Same
P4-2s	SP5-1s	P4-2s	Same
P7-3Ts	/	P7-3Ts	Same
L14-6s	/	L14-6s	Same
L14-6Ns	/	L14-6Ns	Same
V11-3Ws	V11-3WE	/	Same
C11-3s	C11-3s	/	Same
7LT4s	/	7LT4s	Same

- TE7 has the same measurement and calculation functions as the predicated device M9(K141010).

6. Non-clinical Tests:

TE7 Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AAMI / ANSI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO14971 Medical devices - Application of risk management to medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- IEC 62366 Medical devices - Application of usability engineering to medical

devices

- IEC 62304 Medical device software - Software life cycle processes

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

7. Clinical Studies

Not applicable. The subject of this submission, TE7 Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the TE7 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.